



# EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

**Certificate N°:** 304021047RE and ANNEX No. 304021047RE CERTIFICATE  
**Manufacturer:** G. SAMARAS S.A. MEDICAL GAS SYSTEMS  
**Address:** Industrial area of Thermi, 57001  
P.O. Box 60 178, Thermi – Thessaloniki - Greece  
Tel.: +30 2310 46 33 88, - Fax: +30 2314 410113  
**Product:** CYLINDER STATION FOR MEDICAL GASES  
O<sub>2</sub>, N<sub>2</sub>O, N<sub>2</sub>, CO<sub>2</sub>, C.AIR  
(2xm+1xn, m=R/L lots of cylinders n= lots of reserve sources/vessels)  
**Type:**  
MGCYLS 200/8bar, 180m<sup>3</sup>/h @ 8 bar, 2xm+1xn  
MGCYLS 200/8bar, 160m<sup>3</sup>/h @ 8 bar, 2xm+1xn  
MGCYLS 200/8bar, 75m<sup>3</sup>/h @ 8 bar, 2xm+1xn  
MGCYLS 200/8bar, 180m<sup>3</sup>/h @ 4/5 bar, 2xm+1xn  
MGCYLS 200/8bar, 160m<sup>3</sup>/h @ 4/5 bar, 2xm+1xn  
MGCYLS 200/8bar, 75m<sup>3</sup>/h @ 4/5 bar, 2xm+1xn  
**Classification:** Class IIb, (according to Rule 9 & 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14, 1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

<b>EN ISO 11197:2016</b>	Medical supply units
<b>EN ISO 7396-1:2016</b>	Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1)
<b>EN ISO 10524-2:2018</b>	Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators
<b>EN ISO 10524-4 :2008</b>	Pressure regulators for use with medical gases - Part 4: Low-pressure regulators
<b>EN ISO 21969:2009</b>	High-pressure flexible connections for use with medical gas systems
<b>EN 13221:2000</b>	Flexible high pressure connections for use with medical gases
<b>EN 13348:2016</b>	Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum.
<b>EN ISO 5359:2014</b>	Low-pressure hose assemblies for use with medical gases
<b>EN ISO 9170-1:2017</b>	Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum
<b>EN 837-1:1998</b>	Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing
<b>EN ISO 14971:2019</b>	Risk management for medical devices includes risk analysis, evaluation, control and post production information
<b>ISO/DIS 3744:2010</b>	Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane
<b>EN 60601-1:2020</b>	Medical electrical equipment. General requirements for basic safety and essential performance
<b>HD 384:2003</b>	Requirements for electrical installations
<b>EN ISO 15001:2004</b>	Compatibility with oxygen

Thessaloniki, 04/01/2021

Menelaos Samaras  
Legal Representative

CE 0653